

REMARKS

Entry of the foregoing and reexamination and reconsideration of the above-captioned application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112 and in light of the remarks which follow are respectfully requested.

Claims 1, 22 and 35 have been amended, as will be discussed in more detail below, to make it clear that they relate to dosage forms and methods of contraception which exclude the use of substantial amounts of an additional sterilant or contraceptive agent. The support for these amendments is described in greater detail below but can be found throughout the entirety of the specification. The remainder of the amendments to the claims are largely housekeeping. References to "MENT Ac" have been deleted and replaced with a more generic recitation of pharmaceutically acceptable salts thereof. Literal support for this change can be found at page 6, lines 30-31. Similar amendments were made to claims 5-12. In addition, applicants, upon reflection, felt that the term "bioavailable" in claims 9-12 was misplaced and have amended the claims to improve their syntax. Claims 13-15 have been amended to correct a problem with the tense of the word "provide." Similar amendments were made to claims 23-25. None of these amendments constitute new matter nor should they necessitate further searching.

Applicants also wish to bring to the examiner's attention an Information Disclosure Statement which was mailed on February 10, 2000 identifying co-pending application serial no. 09/154,287 and providing the examiner with copies of the references which have been relied on by the examiner handling that application.

Turning to the outstanding rejection, claims 22-37 and 42-44 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-15 of co-pending application serial no. 90/154,287. Applicants acknowledge the provisional nature of the obviousness-type double patenting rejection of these claims and indeed the remaining claims 1-21 and 38-41. Since the co-pending application has not issued, applicants need not address the provisional rejection. Furthermore, applicants believe that the institution of a provisional obviousness-type double patenting rejection is unwarranted in this instance where both of the applications were filed after June 8, 1995 and were filed on the same day. Therefore, at no time could the term of any patent issuing from either application extend beyond that of the term of the co-pending application. Applicants also disagree that the subject matter of the co-pending application renders obvious these claims. However, since the rejection is only provisional at this point, applicants will reserve the right to provide further comment and/or, if and when appropriate, a terminal disclaimer.

Claim 35 stands rejected pursuant to 35 U.S.C. § 102(b) as allegedly being anticipated by Sundaram *et al.* As that same rejection would be applied to the claim as amended, applicants respectfully traverse. The claim now recites that the contraceptive composition "consists essentially of" a non-5- α -reducible androgen in an amount which is sufficient to render a male subject reversibly sterile and a pharmaceutically acceptable carrier. The use of the transitional phrase "consisting essentially of" is consistent with the application's specification. For example, on page 2, lines 11-13, applicants note that the invention is based on, amongst other things, "the discovery that an androgen can be used alone as an effective contraceptive, not merely as an androgen supplement." This is to be contrasted to the contraceptive systems described in the Background of the Invention section in which another drug, something other than an androgen, androgen analog or pharmaceutically acceptable salts thereof, was administered for the purposes of contraception. In those systems, a second drug was coadministered and that second drug could be an androgen. Androgen was not administered, in such instances, for the purposes of contraception. Androgen was instead provided to maintain male sexual function.

Avoiding the use of significant quantities of non-androgen sterilizing agents was clearly the objective of the application and the amendment to claim 35 is completely consistent with that objective. As amended, therefore, the claim excludes the use of dual systems where the androgen was not administered for contraceptive purposes, but merely to maintain male sexual function. The Sundaram *et al.* reference relied upon by the Patent Office teaches just such a dual contraceptive system where androgen was not used for contraception. Nothing in Sundaram *et al.* suggests the use of androgen as a contraceptive at all. Nothing in Sundaram *et al.* suggests that androgen can be used in place of the sterilants described therein and nothing describes a contraceptive composition which excludes sterilizing agents other than androgens. Accordingly, as amended, the claim is not anticipated by Sundaram *et al.*

For much of the same reasons, neither claim 35 nor claims 1-34 or 36 and 37 are rendered obvious by Sundaram *et al.* The Patent Office has taken the position that the prior art teaches that androgen replacement and/or reversible male contraceptive method compositions and dosage forms employing one of the preferred non-5- α reducible androgens were known. The Patent Office has cited the abstract of Sundaram *et al.* and page 202 at column 2, paragraph 1 for support of that position. However, the contraceptive methods and devices described in Sundaram *et al.* are limited to a two implant system, one of which delivers a sterilant for contraceptive purposes and the other delivers an androgen. Clearly, this reference does not teach or suggest to one of ordinary skill in the art that androgen can be

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used without a sterilant for the purposes of contraception. In fact, it teaches quite the opposite. Such a teaching away is strong evidence of nonobviousness.

In addition, nothing in Sundaram *et al.* teaches or suggests the possibility of eliminating the sterilant in favor of the androgen.

Claims 1 and 2 have been amended to make it clear that the methods in question intend to use an androgen, and an androgen only, as the sterilizing or contraceptive agent. Claim 2 has been amended to recite that the method consists essentially of the step of administering a predetermined amount of a non-5- α -reducible androgen which is sufficient to render a male subject reversibly sterile for a predetermined period of time. For the reasons discussed above with regard to claim 35, it is clear that the use of the phrase "consisting essentially of" effectively excludes the possibility of administering a sterilant implant such as that described in Sundaram *et al.* The same is true for the language added to claim 1 which is, essentially, language previously found in claim 16. Applicants do not mean, by these amendments, to exclude the situations where someone adds some relatively inconsequential amount of an additional material which can have sterilizing properties merely as a way of avoiding infringement. However, applicants acknowledge that the use of an androgen as well as a second compound, that second compound being provided in an amount which is sufficient to cause reversible sterilization of a male subject, is in the prior art and that has been excluded by these amendments.

The Patent Office has taken the position that the instant claims differ primarily in that they are drawn to the amounts of androgen which bring gonadotropin and testosterone levels to below specified levels for the purpose of treating nonsterile males. While this is certainly true, it is by no means the only difference or even the primary difference. The primary difference between the present invention and the prior art is that in the present invention, androgen is used as a contraceptive. In the prior art, androgen is not used as a contraceptive. In the prior art, a sterilant is used for contraception.

In accordance with the present invention, androgen alone is used for contraceptive purposes. This is the primary difference. The other differences identified by the Patent Office are acknowledged and should, independently, confer patentability. However, for the reasons explained above, they are not the primary differences. As to the Patent Office's remaining comments about optimization, applicants respectfully submit that the present invention is not merely optimization. Sundaram *et al.* did not even realize the possibility of androgens as a contraceptive.

Turning to claims 38-44, applicants again respectfully traverse. Since it was not previously known that androgens could be used as a contraceptive, it could not have been

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recognized that, to be contraceptively effective, androgens would have to be used in at least a certain level. Conversely, no one could have known that the use of androgen below a certain level, might provide sufficient androgen replacement to be therapeutic without causing what would in those circumstances be an undesired side effect, namely sterility. Accordingly, applicants respectfully submit that claims 36-44 cannot be rendered obvious by Sundaram *et al.*

Should the examiner have any questions with regard to the claims or the amendments made thereto, she should feel free to contact the undersigned, at her convenience, at 908 654 5000. Furthermore, should any fee be due and owing in this regard, the Commissioner is hereby authorized to charge the same to our Deposit Account No. 12-1095.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited.

Respectfully submitted,

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